

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

BNSF RAILWAY COMPANY, on
behalf of THE UNITED STATES OF
AMERICA

Plaintiff,

vs.

THE CENTER FOR ASBESTOS
RELATED DISEASE, INC.,

Defendant.

CV 19-40-M-DLC

FINAL PRETRIAL ORDER

Pursuant to Federal Rule of Civil Procedure 16 and Local Rule 16.4, the parties submit this Final Pretrial Order to govern the course of trial in this matter.

I. Nature of Action.

A. Relator's Statement of the Nature of the Action

The Center for Asbestos Related Disease, Inc. (CARD), was established in 2003 to screen, diagnose and treat patients exposed to asbestos from Libby, Montana. CARD has stated that over 3,414 of its patients have asbestos related disease (ARD) and certified that these patients are eligible for a variety of benefits paid for by the United States. By certifying that these patients carry a diagnosis of ARD on an "Environmental Health Hazard Checklist" (EHH) form, CARD has represented that these patients are eligible for federal benefits. These benefits include EHH Medicare benefits for all health care needs regardless of age; Pilot Program

benefits for gym membership, housekeeping services, travel to medical appointments and other costs not ordinarily covered by Medicare; Drug Prescription costs for Opioid and other narcotic pain medications under Medicare Part D; and Social Security Disability benefits for patients who allegedly cannot work due to asbestos related disease. These programs are all funded by taxpayer dollars.

Relator, the party prosecuting this civil action on behalf of the United States, is the BNSF Railway Company (“BNSF”). Relator alleges that CARD’s own records show that over half of the 3,414 CARD patients submitted for Medicare do not have a radiologist’s finding of structural abnormality in their lungs. Without a valid finding of an asbestos related abnormality on a chest x-ray or CT scan, Relator contends that a CARD diagnosis of ARD is invalid – and false.

In order to be eligible for Medicare coverage according to the language of the Affordable Care Act, an individual *must* have a diagnosis of asbestos related disease. Multiple sources explicitly state that a diagnosis is required for Medicare eligibility. Publications from the Social Security Administration, the Social Security’s Program Operations Manual (“the POMS”); brochures printed by the government; correspondence to CARD from the SSA, and even CARD’s own website all state in writing that in order to be eligible for federal benefits, an individual must have a diagnosis of asbestos related disease.

CARD's main vehicle for submitting claims for Medicare and other federal benefits is an Environmental Health Hazards Checklist Form, or an "EHH." The EHH form is filled out by the CARD Physician and submitted to the Social Security Administration ("SSA") Field Office in Kalispell, Montana. The EHH form itself includes a box for the physician's signature, the date of diagnosis of the asbestos-related impairment, and the nature of asbestos-related condition.

It is an undisputed fact in this case that CARD has submitted EHH forms to the Social Security Administration when CARD providers were aware that individual patients did not have a clinical diagnosis of asbestos-related disease. It is also an undisputed fact that CARD has submitted patients without a diagnosis of asbestos-related disease to the Social Security Administration for Medicare benefits since at least 2013 and presumably since the Affordable Care Act was passed in 2010.

CARD maintains that a chest x-ray or a CT scan interpreted by a non-diagnosing radiologist called a "B-reader," by itself satisfies the requirements for Medicare eligibility. But it is an undisputed fact that B-readers do not diagnose patients, B readers do not sign EHH forms, and that B reads are not used by CARD for any diagnostic purpose. Furthermore, the Social Security Administration, through a sworn witness, recently described the practice of submitting patients for

Medicare benefits on a B-read alone – when CARD knew there was no diagnosis of asbestos related disease – as fraud.

Relator contends that by submitting EHH forms on behalf of CARD patients who have no valid signs of asbestos-related disease, any federal benefits claimed constitute false claims. Medical records and witness testimony will show that patients who have been told by CARD they are not sick from any asbestos related disease – are still receiving benefits including gym memberships and housekeeping services under the EHH Noridian Pilot Program. Other patients with no radiologists' findings of ARD are receiving Social Security Disability benefits and Medicare Part D payments for CARD prescriptions for opioid and narcotic pain medications. Relator contends that none of these benefits are medically necessary for patients who have no valid diagnosis of asbestos related disease.

A separate category of alleged false claims is related to CARD's federal grants. CARD has submitted grant paperwork to the United States claiming over \$20M in federal grant funds. In that paperwork, Relator alleges that CARD included false information about its diagnosis rate and diagnostic methodology. Relator alleges that CARD minimizes the diagnostic dissension rate between a CARD interpretation of CT scans and outside radiologists' reads of radiographic studies of CARD patients while concealing the truth about CARD's practices from the government.

B. Defendant's Statement of the Nature of the Action

Libby was the site of a vermiculite mining and processing operation from the 1920s through 1990. While in operation, Libby was the world's largest source of vermiculite. Libby vermiculite is contaminated with a highly toxic amphibole asbestos. This has resulted in substantial asbestos-related illness and death not only in vermiculite workers, but family members, and residents with no occupational exposure.

In 1999, reports of pervasive asbestos-related disease in Libby prompted a concerted response by the federal government, a large component of which was community-based screening by the Agency for Toxic Substances and Disease Registry (ATSDR). In 2010, Congress included language in the Affordable Care Act (ACA, Public Law 111-148) to continue to make screening available to persons with potential exposure to vermiculite while they resided in the Libby area.

Pursuant to the Affordable Care Act, 42 USC §1881A(e)(2)(B)(i)(I)-(II), the "diagnosis" for "Asbestosis, pleural thickening, or pleural plaques" is "established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or (II) such other diagnostic standards as the Secretary specifies, except that this clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring

medical treatment as a result of these diagnoses.” Physicians at CARD are “qualified physicians” for purposes of the ACA.

In 2011, ATSDR awarded a four-year grant to CARD to conduct screening activities under the ACA. For purposes of the ATSDR grant, a screened individual was deemed positive if interpretation of computed tomography (CT) of the chest by qualified physicians (a physician with board certification in radiology or pulmonary medicine or an interpretation provided by the CARD Clinic, for patients in the Libby area) established that asbestosis, pleural thickening, or pleural plaques were present, or if interpretation of a plain x-ray of the chest by a B-Reader establishes that asbestosis, pleural thickening, or pleural plaques are present. Persons with positive screening results may be eligible for Medicare benefits.

ATSDR awarded two subsequent grants to CARD, essentially extensions of 2011 grant, for the periods 2015-19 and 2019-24. As part of compliance with the terms of the grants, CARD has submitted annual reports and budget justifications to ATSDR; submitted quarterly reports to ATSDR; and CARD staff has worked closely with ATSDR to ensure compliance with the terms of the grants. Almost all of CARD’s funding comes from the ATSDR screening grants.

Screening initially consists of a one-page application and proof of presence to determine if a person has sufficient exposure history and latency to qualify for

screening under the ATSDR grant, an interview, exposure history and medical history questionnaires, spirometer test, posterior-anterior chest x-ray, and visit with a CARD medical provider. If determined appropriate by CARD medical providers, the patient is scheduled for a CT scan, which is then read by a radiologist, typically located where the CT scan is performed.

CARD physicians apply American Thoracic Society (ATS) guidelines when making positive asbestos-related disease (ARD) diagnoses. Per the guidelines, in addition to structural radiographic abnormalities, clinically positive determinations of ARD are made by CARD's medical providers based on individual evaluation of sufficient exposure, adequate latency, physical evaluation including symptoms assessment and ruling out other plausible causes of clinical and radiographic abnormalities.

If CARD physicians determine that a patient has an asbestos-related disease and the patient requests it, CARD staff fill out an Environmental Health Hazards (EHH) checklist for signature by a CARD physician. CARD forwards the EHH checklist to the Social Security Administration. Patients who are diagnosed with an asbestos-related disease by CARD physicians as noted on the EHH checklist are eligible for Medicare benefits under the Affordable Care Act. After passage of the Affordable Care Act in 2010, the Social Security Administration devised the EHH checklist that CARD uses. After the Affordable Care Act became law, and

continuing today, CARD staff has worked closely with the SSA to implement the new provisions of the Affordable Care Act. Notably, SSA presented CARD with an award for its “Outstanding Partnership with SSA in Medicare Outreach to Individuals with Asbestos Related Disease.”

As part of the ATSDR grants, CARD established a panel of B-Readers to review plain chest x-rays and outside readers to review CT scans of screening participants, and CARD staff send radiographic images of patients to these readers for interpretation. The outside readers fill out a form for each radiograph or CT scan they interpret and send the forms back to CARD. If an outside reader interprets an asbestos-related condition or a qualifying condition on a radiographic image, and the patient requests it, CARD staff fill out an EHH checklist and designate that the asbestos-related condition or qualifying condition was determined by an outside reader. This is a designation not required on the EHH checklist, but used for recordkeeping and grant reporting by CARD. The EHH checklist is then signed by a CARD physician. CARD forwards the EHH checklist to the Social Security Administration. Outside reader interpretations do not play a role in the diagnostic decisions of CARD physicians.

Because the §1881A of the Affordable Care Act states that the “diagnosis” for “Asbestosis, pleural thickening, or pleural plaques” is “established by (I) interpretation by a ‘B Reader’ qualified physician of a plain chest x-ray or

interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary,” CARD physicians fill out an EHH Checklist for individuals when

- 1) CARD physicians make a clinical diagnosis of asbestosis, pleural thickening, or pleural plaques; and when
- 2) A B-Reader establishes asbestosis, pleural thickening, or pleural plaques by an interpretation of a chest x-ray; or a qualified physician radiologist establishes asbestosis, pleural thickening, or pleural plaques by an interpretation of a computed tomographic radiograph of the chest, even though CARD physicians did not diagnose the patient with an asbestos-related disease.

CARD physicians make clinical diagnoses. B-Readers of chest x-rays and outside readers of CT scans do not make clinical diagnoses, they interpret x-rays and radiographs. In order to comply with §1881A, CARD physicians recognize that those patients whom CARD did not clinically diagnose with asbestosis, pleural thickening, or pleural plaques also qualify for Medicare benefits under §1881A if a B-Reader or outside CT reader establishes asbestosis, pleural thickening, or pleural plaques by an interpretation of a chest x-ray or CT scan, even though CARD physicians do not believe the patient has asbestosis, pleural thickening, or pleural

plaques. Medical diagnoses by physicians are not equivalent to a diagnosis as described in §1881A.

The SSA designated deponent has testified that the SSA defers to the provider filling out the EHH Checklist to determine if a patient meets the “minimum medical evidence required” for Medicare benefits. CARD physicians believe that §1881A clearly directs that a “diagnosis” for purposes of the law is established not only by CARD clinical diagnoses, but also by positive interpretations by outside readers.

There is significant discordance in interpretations of CT scans by CARD’s physicians, local radiologists’ interpretations, and outside readers’ interpretations. ATSDR is aware of this discordance, and has worked closely with CARD on reports on the grants since funding of the screening program began in 2011.

II. Jurisdiction and Venue.

This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. §3732(a) (False Claims Act) and 28 U.S.C. § 1331 (Federal Question). Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and 31 U.S.C. § 3732(a) because CARD can be found and/or resides in the District of Montana, and CARD transacts business within this district and the facts forming the basis of this Complaint occurred within this district.

III. Jury.

This case is set for trial before a jury. Neither party contests trial of any issue by the jury.

IV. Agreed Facts.

1. CARD is a Montana non-profit corporation. Its registered agent for service of process is Tracy McNew, 214 East 3rd Street, Libby, Montana 59923.

2. Defendant, CARD, was born, and evolved, in response to raised awareness of asbestos exposure in the Libby, Montana area that surfaced in 1999. In 2000, CARD was established as a department of St. John's Lutheran Hospital to provide screening, diagnosis, treatment and monitoring for those exposed to Libby amphibole asbestos. In April 2003, CARD separated from St. John's Lutheran Hospital and became a stand-alone organization.

3. Since its inception, CARD and its medical providers have screened thousands of patients for the presence of Asbestos Related Disease ("ARD").

4. CARD states in its Patient Education literature that it, "provides a comprehensive asbestos health screening that is important for all people with a history of asbestos exposure in Lincoln, County."

5. CARD further states that it provides: "Specialty Libby Amphibole Pulmonary Health Care: Disease management and treatment services are available at the CARD Clinic in Libby, Montana. This specialty care is valuable for the

approximately 7,000 patients followed by CARD and the new patients who present daily for screening assessment and information regarding the possible effects of their asbestos exposure.”

6. CARD is primarily funded by the receipt of federal grant monies administered by the Agency for Toxic Substances Disease Registry (“ATSDR”) which is part of the Centers for Disease Control (“CDC”).

7. Since 2011, CARD’s primary screening grant awards have totaled approximately \$2.4M annually: “PPHF-14-Libby Montana’s Public Health Emergency: Asbestos Health Screening” (Grant #U61TS000179 from 2011-2015; Grant #NU61TS000251 from 2016-2018 and Grant # NU61TS000295 in 2019).

8. From 2011 until the present, CARD has been awarded over \$20M dollars in federal funds through the primary screening grant alone.

9. The first four-year grant period ran from July 1, 2011, to June 2015.

10. The federal government extended the grant by another four years on August 21, 2015.

11. The term of this extension ran from September 1, 2015, to August 31, 2019 at a rate of between \$2.3M and \$2,499,995 per year.

12. The federal government extended CARD’s grant by another five years on July 19, 2019.

13. These grant funds pay for CARD staff salaries, education and outreach related to Asbestos Related Disease (“ARD”) and for screening services and radiographic studies such as chest x-rays and Computed Tomography (CT scans).

14. As a condition of these grant monies, CARD has reporting requirements related to the scope of CARD’s screening program and the expenditure of grant funds as set forth by federal law. *See* C.F.R. 74 et seq. (2011).

15. The Medicare Pilot Program for Asbestos Related Disease (“Pilot Program”) provides comprehensive care for individuals diagnosed with a qualified asbestos related condition, including services not normally covered under Medicare, for residents in Lincoln, Flathead, Glacier, Lake, Mineral, Missoula, and Sanders counties in Montana or Ferry, Lincoln, Pend d’Orielle, Spokane, Stevens, and Whitman counties in Washington, or Benewah, Bonner, Boundary, Clearwater, Kootenai, Latah, and Shoshone counties in Idaho.

16. Subsequent to its creation in 2011, individuals enrolled in the Pilot Program were entitled to Medicare coverage benefits for complete healthcare, not just asbestos related healthcare.

17. These Medicare coverage provisions appear in a special section of the affordable Care Act specifically focused on the diagnosis of asbestos related disease. This provision is titled “Medicare coverage for individuals exposed to environmental health hazards.” 111 Pub. L. No. 111-148, § 10323, 124 Stat. 119, 954 (2010) [42

U.S.C. § 139rr-l]; amending Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.) by inserting 42 U.S.C. § 1881A.

18. A qualifying condition for Medicare coverage and Pilot Program benefits is that CARD patients must be diagnosed with one of the qualifying conditions on the Environmental Health Hazards Checklist.

19. Three of the primary qualifying impairments are “Asbestosis, pleural thickening, or pleural plaques” 42 U.S.C. § 1881A(e)(2)(B)(i).

20. “Asbestosis” and “Pleural thickening/Pleural plaques” share an EHH Checklist Diagnosis Code of “5010”.

21. The “Environmental Health Hazards Checklist” Form (“EHH”) is signed and dated by a physician and submitted by CARD to the federal government to allow CARD patients to get an EHH designation on their Medicare coverage.

22. The EHH Checklist quotes parts of 42 USC § 1881A(e)(2)(B)(i)(I)&(II).

23. CARD stated in its Answer that CARD’s diagnoses of ARD have been based on American Thoracic Society (ATS 2004 criteria).

24. In order to satisfy ATS 2004 criteria, a diagnosis of ARD must include:

(a) Evidence of structural pathology consistent with asbestos related disease as observed by imaging (chest x-ray or CT scan) or histology (microscopic examination);

(b) Evidence of causation by asbestos as documented by the occupation and environmental history, markers of exposure (usually pleural plaques), recovery of asbestos bodies or other means;

(c) Exclusion of alternative plausible causes for the findings.

25. Dr. Black has been with CARD since the clinic's inception.
26. Dr. Black is a pediatrician by specialty.
27. Dr. Black is not a board-certified pulmonologist.
28. Dr. Black is not a board-certified radiologist.
29. Dr. Black is not a Certified B Reader.
30. CARD does not currently employ a board-certified pulmonologist, a board-certified radiologist, or a NIOSH certified B Reader.
31. No medical care providers at CARD are certified, licensed or formally trained as radiologists or formally trained or credentialed in diagnostic radiographic interpretation.
32. No staff or employees at CARD are certified or formally trained radiology technicians.
33. Furthermore, CARD's facility has no x-ray or CT scanning equipment on site.
34. Dr. Black and other medical providers at CARD have diagnosed lamellar pleural thickening as an asbestos-related disease.

35. Dr. Black claims that signs of asbestos related disease caused by the Libby amphibole are nonspecific and difficult to detect.

36. Dr. Black has stated that he can perceive signs of asbestos related disease on CT scan caused by the Libby amphibole, and Dr. Black has stated, “what the mind does not know, the eye does not see.”

37. Lamellar pleural thickening is a basis for CARD’s certification on EHH Checklists forms that patients have an asbestos related disease.

38. CARD’s contract with ATSDR requires radiologists to review x-rays and CT scans.

39. One provision of the grant award language states that *all radiologic exams will be sent for outside reads to a panel of expert B-readers and radiologists that will be established by CARD and ATSDR.*

40. Lincoln County received a grant in 2009 for asbestos screening.

41. Radiology technicians take x-rays and CT scans of CARD patients.

42. Images ordered by CARD at Cabinet Peaks are read by a local radiologist.

43. CARD’s ATSDR grant requires an outside read radiologist panel, which is composed of five radiologists who are NIOSH-certified B readers, and three of whom are thoracic radiologists.

44. CARD physicians often diagnose patients with ARD before the patient's CT scan is interpreted by qualified outside radiologists.

45. It is well-known to CARD and its staff that CARD often diagnoses patients without an outside radiologist's CT interpretation.

46. Internal data generated by clinic staff as part of the federal grant requirement shows that CARD is aware of the results of every outside CT and chest x-ray interpretation received by CARD.

47. CARD is aware of the differences between the readings of CT scans by Dr. Black and outside radiologists.

48. CARD has diagnosed patients with ARD whose CT scans were not found to have abnormalities by thoracic radiologists on the B reader panel.

49. The fact that an "abnormality" exists does not mean that the outside CT reader has diagnosed the patient with ARD. This merely signifies that the patient's CT showed signs that might be "consistent with" ARD.

50. Abnormalities could be consistent with rib fractures, prior thoracic surgery, radiation therapy, or the use of certain medications, or autoimmune disease.

51. As part of its federal grant requirements, CARD submits CT scans to the aforementioned "Peer Review" panel of radiologists.

52. Since 2010, CARD has submitted over two-hundred CT scans to its peer review panel that Dr. Black has read as positive for signs of asbestos related disease.

53. The peer review panel selected by ATSDR to review CT scans often disagrees with Dr. Black's diagnoses.

54. CARD submitted all of its patients diagnosed with ARD for Medicare coverage if the patient so desired.

55. Federal grant awards to organizations and individuals are predicated on true and accurate grant applications and other statements to the federal government.

56. Receipt of grant awards also involves certain continuing conditions, responsibilities and obligations: "These responsibilities include accountability for the appropriate use of funds awarded and the performance of the grant supported project or activities as specified in the approved application." See U.S. Dept. of Health and Human Services, *HHS Grants Policy Statement* (January 1, 2007); <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>

57. One of the conditions involved in obtaining federal grant funds is to share true, accurate and complete information with the granting agency. Penalties, including revocation of the grant, can be imposed if information contained in or submitted as a part of a grant application or other required reports is found to be

false, fictitious or fraudulent. *Id.* at p. I-7 et seq.; *See* 45 C.F.R. pt. 74 (2011); *See also* 45 C.F.R. § 79.3 (2011).

58. Another condition for keeping and renewing these government grants, is that CARD must certify that all federal monies used are consistent with the original grant purpose. 45 C.F.R. § 74.20 et seq. (2011).

59. CARD has an annual audit and prepares an Annual Progress Report, a Final Progress Report, and a Federal Financial Report.

60. These reports are uploaded by CARD to the grants management system, and expenses are reimbursed by grant funds.

61. These same federal provisions also require that grant recipients must take steps to avoid fraud, waste or abuse of government funds and must report any knowledge of fraud, waste or abuse to the government. *Id.*; 45 C.F.R. § 74.51 et seq. (2011); 45 C.F.R. pt. 74, app. E (2011).

62. CARD requests reimbursements through the grants management system, called GrantSolutions.

63. By accepting the award, and drawing from funds, the recipient (CARD) acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award.

64. The federal government has awarded CARD grant money totaling approximately \$500,000 annually to pay outside readers to interpret CT scans and x-rays.

65. CARD diagnoses patients before outside CT scan reports are received by CARD.

66. “Outside” CT interpretations do not arrive at CARD until months after patients have already been diagnosed.

Medicare Without a Diagnosis

67. CARD does not consider B-reader chest x-ray or reports for any asbestos-related diagnostic purposes.

68. Pursuant to rules governing federal grants (referenced herein) CARD itself has an obligation to prevent and report fraud, waste and abuse related to its own use of any federal grant funds. 45 C.F.R. pt. 74 et seq. (2011).

69. CARD has also received “sub award” grant funding from the Mount Sinai School of Medicine in New York.

70. This sub award grant exceeded \$300,000 in 2013 (Prime Award No. 5 R01 TS000099-04); (Sub Award No. 0254-5674-4609).

71. Like other federal grant awards CARD receives, by drawing down or otherwise obtaining funds from the grant payments system, the recipient acknowledges acceptance of the terms and conditions of the award and is obligated

to perform in accordance with the requirements of the award. 45 C.F.R. pt. 74 et seq. (2011).

72. By drawing funds, the federal grant Awardee certifies that proper financial management controls and accounting systems to include personnel policies and procedures have been established to adequately administer Federal awards and funds drawn down are being used in accordance with federal cost principles, regulations and the President's Budget and Congressional Intent.

73. As part of the Subaward Agreement, CARD stated that there were no conflicts of interest or "Significant Financial Interests" that prevented the receipt of federal grant monies from the Prime Award.

74. CARD clinicians have a long-standing personal and professional relationships with Mount Sinai clinicians.

75. Both CARD and Mount Sinai study and treat ARD.

76. Dr. Black serves as an adjunct professor at Mount Sinai School of Medicine.

77. Dr. Black and Mount Sinai doctors have co-authored studies on asbestos related issues in the past.

78. The program director and principal investigator of the Mount Sinai Prime Award was a B Reader funded by CARD's grants.

79. According to Mount Sinai grant sub award documents, Dr. Black and other CARD staff members were paid a total of \$137,112 in salary from Mt. Sinai sub award funds.

80. The sub award also awarded CARD \$106,808 for “Patient Care Costs.”

81. That sub-award issued CARD \$5,500 for “CT scans only at CARD.”
(Sub Award No. 0254-5674-4609).

82. CARD has not ever had a CT scanner at its facility.

83. By accepting the Mount Sinai funds, CARD certified that it had no conflicts of interest and that the funds would be used in accordance with federal rules and regulations governing federal grants.

84. When CARD diagnoses patients with ARD, the diagnosis is notated on the Environmental Health Hazards Checklist and this qualifies patients for Medicare coverage.

85. CARD’s patients who are enrolled in Medicare have their medical treatments covered by Medicare.

86. When CARD diagnoses patients with asbestosis or pleural thickening pleural plaques, the diagnosis is notated on the Environmental Health Hazards Checklist, and this may help qualify patients for Social Security Disability benefits.

87. When CARD diagnoses patients with asbestosis or pleural thickening pleural plaques, the diagnosis is notated on the Environmental Health Hazards Checklist and CARD provides patients with Form SSA-827.

88. CARD has a case manager whose responsibilities include assisting CARD patients with Pilot Program benefits.

89. When CARD diagnoses patients with asbestosis or pleural thickening pleural plaques, the diagnosis is notated on the Environmental Health hazards Checklist, and CARD provides patients with Pilot Program forms.

90. CARD physicians have prescribed narcotic and opioid pain medications.

91. These prescription pain medications include scheduled opioid drugs and narcotic painkillers including Oxycodone, Hydrocodone, OxyContin, Vicodin, Lortab, Percocet, Tramadol, Codeine, Morphine, Fentanyl and other controlled substances.

92. CARD has patients on disability status due to ARD who receive opioid pain medication.

V. Elements of Liability

1. False Claims Act (31 U.S.C. §§ 3729-33 *et seq.*)

Relator's *prima facie* False Claims Act case against the Center for Asbestos Related Disease consists of the following elements:

1. First, Defendant CARD knowingly presented or caused to be presented, or knowingly made, used or caused to be made or used a false statement or record to get a false or fraudulent claim paid or approved by the government;
2. Second, the statement or record was false or fraudulent;
3. Third, the statement or record was material to a decision by the government to pay a false or fraudulent claim; and
4. Fourth, Defendant CARD had sufficient knowledge that the statement or record was false or fraudulent.

For purposes of this False Claims Act case, Defendant has “sufficient knowledge” if one of the following is true:

- (a) Defendant had actual knowledge of the falsity of the information; or
- (b) Defendant acted in deliberate ignorance of the truth or falsity of the information; or
- (c) Defendant acted in reckless disregard of the truth or falsity of the information.

It is not necessary for Relator to prove that Defendant acted with actual intent to defraud anyone, nor is it necessary for Relator to prove actual damages in this matter.

There are three main categories of false claims alleged in this matter. First, Defendant CARD allegedly made false statements and false claims on Environmental Health Hazards Checklist Forms submitted to the Social Security Administration in Kalispell, Montana, related to Medicare Benefits on behalf of CARD patients who did not have a valid diagnosis of asbestos related disease. The submission of these EHH forms led to payment of medical bills by the government to CARD, pharmacists and other medical providers. Second, by certifying EHH forms and sending documents indicating patients had been diagnosed with ARD, and by indicating certain treatments and benefits were medically necessary, CARD caused to be presented claims based on false records and information for Noridian Pilot Program benefits, Medicare Part D benefits for opioid and narcotic prescription drugs under Medicare Part D and Social Security Disability benefits. Third, CARD obtained several federal grants from the Agency for Toxic Substances and Disease Registry (“ATSDR”) that serve as the predominant source of CARD’s funding based on grant claim forms, grant reports and other records that contained false information.

VI. Defense Elements

Claims under the FCA require a showing of “(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material,

causing (4) the government to pay out money or forfeit moneys due.” *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 902 (9th Cir. 2017).

CARD sends Environmental Health Hazards (EHH) Checklists to the SSA based on its own clinical diagnoses of asbestos related diseases, as well as determinations of outside readers of positive interpretations of x-rays and CTs. BNSF argues that when CARD sends EHH Checklists based solely on outside reads it constitutes false claims because CARD has not diagnosed the patients with an asbestos related disease, and an outside read is not sufficient to establish a diagnosis.

CARD follows §1881A, which establishes that “any individual who is diagnosed with” “asbestosis, pleural thickening, or pleural plaques as established by (I) interpretation by a ‘B Reader’ qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or (II) such other diagnostic standards as the Secretary specifies.” Thus even if CARD does not diagnose a patient with asbestosis, pleural thickening, or pleural plaques, if a qualified physician establishes asbestosis, pleural thickening, or pleural plaques by interpretation of an x-ray or CT, CARD believes that §1881A requires that CARD submit EHH Checklists for those individuals.

CARD works closely with ATSDR and ATSDR designated representatives Theodore Larson testified that CARD is in full compliance with all reporting requirements and ATSDR is aware of diagnostic discordance between CARD physicians and other physicians.

VII. Relief Sought

Pursuant to 31 U.S.C. §§ 3729(a)(1)(A) *et seq.*, Relator claims special damages, treble damages on special damages, statutory penalties and attorney fees related to over 500 individual false claims for Medicare eligibility, Noridian Pilot Program benefits, Social Security Disability benefits and Medicare Part D (Opioids) benefits that CARD presented or caused to be presented for payment or approval to the federal government. Additionally, Relator claims special damages and statutory penalties for each false statement related to the grant fraud claims made by CARD for funds from the ATSDR/CDC. These individual claims are set forth in Exhibit 1 to Relator's Third Amended Complaint.

By virtue of the false records and statements knowingly made, used or caused to be made or used, CARD is liable to the United States government for civil penalties of not less than \$5,500 and not more than \$23,607 for each individual false claim, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus three times the amounts of actual damages which the government sustained because of the acts of Defendant.

Relator requests that the Court award damages for:

1. Actual Damages in an amount equal to the costs paid by the government as a result of CARD's False Claims.
2. Civil Penalties in an amount three times the actual damages suffered by the government.
3. Imposition of statutory monetary penalties of not less than \$5,500 and not more than \$23,607 for each individual false claim as allowed under 31 U.S.C. §§ 3729 *et seq.*
4. Attorney's fees and costs;
5. Pre-judgment and post judgment interest as appropriate;
6. For such other and further relief as the Court deems just and proper.

VIII. Legal Issues

A. Relator's Legal Issues:

1. **Exclusion of CARD's undisclosed Expert Opinions and undisclosed lay witnesses**

Relator filed Motions *in Limine* (Doc. 85) and Motions to exclude CARD's undisclosed expert and lay witnesses. These motions were briefed and rulings provided (Doc. 132).

Based on this Court's Order excluding any previously undisclosed expert and lay witness testimony (Doc. 132), Relator renews its motion to

exclude undisclosed and irrelevant expert testimony from Senator Max Baucus. Relator further moves to exclude undisclosed and irrelevant expert testimony from Dr. Jaime Szeinuk and undisclosed and irrelevant lay witness testimony from CARD patients Jimmie Sevre, Gayla Benefield and Judy Woller. Relator's trial brief addresses these topics.

2. Discovery Violations related to Communications between CARD and SSA

Relator recently learned of emails between CARD and SSA that were not produced prior to the May 16, 2023, deposition of SSA 30(b)(6) deponent Heather Hillman. In fact, these emails were not disclosed by CARD, rather their existence was uncovered *during the deposition* as Relator's counsel questioned the witness. At that point in the deposition, counsel took a break so that the emails referenced by the SSA witness could be examined. During that break, CARD counsel indicated that there were approximately 2,500 emails he had received from CARD the night before. CARD counsel provided these emails after the deposition concluded. Counsel may have disclosed attorney-client communication within those 2,500 emails. It is anticipated that this topic will likely come up at the Pre-Trial Conference on June 8, 2023.

These emails were requested by Relator in discovery years ago. CARD's initial discovery responses clearly indicate it was on notice of this request as early as 2021. (*See* Doc. 93-23). Relator's trial brief addresses this

topic.

3. Anticipated Trial Motions for Jury Instructions and/or Directed Verdict

Relator filed a Motion for Summary Judgement related to CARD's submission of undiagnosed patients for Medicare benefits (Doc. 78). This Court denied Relator's motion. (Doc. 131). However, the Court stated in its Order that:

“CARD has not provided a statement from the SSA supporting their argument that the SSA was fully informed as to CARD's practices regarding EHH coverage certification. BNSF argues that CARD has been falsely or fraudulently certifying patients for EHH Coverage and misrepresenting their own practices to the SSA. However, neither party has produced sufficient evidence to justify granting summary judgment on this issue.”

(Doc. 131 at pg. 5-6) (internal citations omitted).

Recent testimony from the SSA may change the Court's view of these issues. Relator's trial brief addresses these topics.

B. Defendant's Legal Issues

1. Testimony of Max Baucus

Max Baucus was disclosed as an expert and his expected testimony was disclosed in the form of a signed declaration. The Court ordered that BNSF could depose him. Parties took his testimony for trial and will present it on video during trial.

2. Testimony of Jaime Szeinuk

Dr. Szeinuk was not disclosed as an expert witness. His factual testimony was also recorded and will be presented on video during trial.

3. SSA emails

CARD sent counsel a set of SSA emails on May 16, 2023. In order to get them to BNSF as soon as possible, counsel provided the emails via flashdrive to BNSF counsel on May 16 without reviewing the emails. It turns out the email tranche included several attorney-client privileged emails from 2023 and counsel later asked BNSF counsel to delete and disregard them. The bulk of the emails between CARD and SSA were previously produced to BNSF on December 3, 2021.

4. USA's limine motion

The USA has moved in limine to prevent certain testimony from its SSA Rule 30(b)(6) deponent to be admitted at trial, including personal opinions and legal conclusions. Parties also will take testimony from another SSA deponent on June 8, 2023.

IX. Discovery Documents

Relator may offer the following discovery documents:

1. BNSF's Initial Disclosures
2. BNSF's Supplemental Initial Disclosures, May 20, 2022

3. BNSF's Second Supplemental Initial Disclosures, February 27, 2023
4. CARD's Initial Disclosures, August 30, 2021
5. CARD's Responses to BNSF's Requests for Admission, October 14, 2021
6. CARD's First Supplemental Responses to BNSF's First Discovery Requests, October 17, 2021
7. CARD's Responses to BNSF's First Requests for Production, December 9, 2021
8. CARD's Responses to BNSF's Second Discovery Requests, March 3, 2022
9. CARD's Responses to BNSF's Third Discovery Requests, March 3, 2022
10. CARD's Initial Disclosure First Supplement, May 13, 2022
11. CARD's Initial Disclosure Second Supplement, May 8, 2023

Defendant may offer the following discovery documents:

1. CARD subpoena to SSA
2. CARD subpoena to ATSDR
3. Discovery listed by BNSF

X. Estimate of Trial Time

The parties estimate that Relator will require 10 days of trial to complete its case in chief. CARD estimates it will require 3-4 days to complete its case in chief.

XI. Witnesses

Attached as Exhibits 1 and 2 are Relator's Will Call and May Call Witness Lists. Attached as Exhibit 3 are CARD's Will Call and May Call Witness Lists. Attached to the Witness lists are Relators' deposition designations and CARD's deposition designations. Objections and counter-designations are anticipated from CARD prior to the Pre-trial conference on June 8, 2023.

XII. Exhibits

Attached as Exhibits 4 and 5 are Relator's Will Offer and May Offer Exhibit Lists. Attached as Exhibit 6 are Defendant CARD's Will Offer and May Offer Exhibit Lists.

XII. Supersession

This Order supersedes the pleadings in this matter.

DATED this 8th day of June, 2023.



Dana L. Christensen
UNITED STATES DISTRICT JUDGE

Approved as to form and content:

KNIGHT NICASTRO MACKAY, LLC

/s/ W. Adam Duerk
Attorney for Relator

BECHTOLD LAW FIRM, PLLC

/s/ Timothy M. Bechtold
Attorney for Defendant